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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.          | CONFIRMATION NO. |
|--|-------------|----------------------|------------------------------|------------------|
| 09/863,849   | 05/23/2001  | Jerome O. Cantor     | C35795/125237                | 1932             |
| 7590 11/23/2005<br>BRYAN CAVE LLP<br>1290 AVENUE OF THE AMERICAS<br>NEW YORK, NY 10104 |             |                      | EXAMINER<br>HENRY, MICHAEL C |                  |
|  |             |                      | ART UNIT<br>1623             | PAPER NUMBER     |
| DATE MAILED: 11/23/2005  |             |                      |                              |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/863,849

Applicant(s)

CANTOR ET AL.

Examiner

Michael C. Henry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 31-33 and 37-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38-41 and 44 is/are allowed.
- 6) ☒ Claim(s) 31-33, 37, 42, 43 and 45-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

The following office action is a responsive to the Amendment filed, 09/01/05.

The amendment filed 09/01/05 affects the application, 09/943,650 as follows:

1. Claims 1-30 and 34-36 have been canceled. New claims 37-47 have been added.

This leaves claims 31-33, 37-47. Upon further consideration the examiner has determined that the indicated allowable subject of the previous office action is not appropriate and is withdrawn or rescinded. Consequently, this office action is made non-final.

The responsive to applicants' arguments is contained herein below.

Claims 31-33, 37-47 are pending in application

#### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31-33, 37, 42, 43, 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cantor (US 5,633,003) in combination with Green (WO 96/19968).

In claim 31, applicant claims "A system for delivering a polysaccharide formulation to a respiratory tract of a mammal, comprising: a mixture comprising a polysaccharide having a molecular weight of between about 50,000 and  $1.5 \times 10^6$  Daltons at a concentration of less than about 5.0 mg/ml (w/v) of polysaccharide, and a breathable fluorocarbon propellant; a canister

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adapted to contain said mixture under pressure; a valve connected to said canister for regulating delivery of said mixture; and a nozzle interconnected with said valve for transforming said mixture under pressure into an inhalable aerosol mist when said valve is actuated.” Dependent claim 32 is drawn to said composition or system comprising the polysaccharide in the aerosol mist is of specific median mass distribution sizes. Claim 33 and 37 are drawn to said system or composition wherein the said mixture further comprises a drug and specific drugs. Claims 34, 37-40, 42, 43, 45-47 are drawn to said system or composition wherein the polysaccharide is chemically modified, wherein the said solution further comprises a drug and specific drugs, wherein the polysaccharides are specific polysaccharides and are of specific molecular weights.

Cantor discloses a system for delivering a polysaccharide formulation to a respiratory tract of a mammal, comprising: a mixture comprising a polysaccharide (hyaluronic acid), that can be delivered via a route aerosol inhalation by a nebulizer (see col. 3, METHODS, lines 46 to col. 4, line 45; also, see abstract). In addition, Cantor uses the same method of delivery (aerosol inhalation) for the same purpose (i.e., treating respiratory disorders) comprising a polysaccharide. Furthermore, it should be noted that the nebulizer contains the said canister, valve and nozzle, claimed by applicant.

Green discloses an aerosol formulation for administration by inhalation containing a medicament, a sugar (a carbohydrate) and a fluorocarbon propellant for treating respiratory disorders (see abstract). Green discloses that the medicament can include drugs such as terbutaline, penicillins, ephedrine (see page 2, line 22-page 3, line 9). It should be noted that Green, like Cantor, also uses the same method of delivery (aerosol inhalation) for the same purpose (i.e., treating respiratory disorders).

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The difference between applicants' claimed composition and the composition of Cantor is that Cantor does not disclose the concentration, molecular weight or particle size of the polysaccharide and Cantor does not use a drug or propellant. However, Green discloses that drugs such as terbutaline, penicillins, ephedrine and a propellant such as a fluorocarbon, can be used as an inhalant in the inhalant aerosol formulation (see page 2, line 22-page 3, line 9; see abstract).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared the composition of Cantor comprising different concentrations, molecular weights or particle size of the polysaccharide in combination with a drug disclosed by Green such as terbutaline, penicillins, ephedrine and a fluorocarbon propellant to be used as an inhalant aerosol formulation for treating respiratory conditions or disorders, depending on need (like the severity of the respiratory disorder).

One having ordinary skill in the art would have been motivated, to prepare the composition of Cantor comprising different concentrations, molecular weights or particle size of the polysaccharide in combination with a drug disclosed by Green such as terbutaline, penicillins, ephedrine and a fluorocarbon propellant to be used as an inhalant aerosol formulation for treating respiratory conditions or disorders, depending on need (like the severity of the respiratory disorder). More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980). It should be noted that claims 38-41 and 44 appear to be free of the prior art of record.

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***Response to Amendment***

Applicant's arguments with respect to claims 31-33 have been considered but are moot in view of the new ground(s) of rejection.


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

November 10, 2005.

  
SAMUEL BARTS  
PRIMARY EXAMINER  
GROUP 1200